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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
UNGAR, SUSAN NMN	
ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 03/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	09/762,021	SUN ET AL.	
	Examiner	Art Unit	
	Susan Ungar	1642	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 23 January 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☐ The period for reply expires *three* months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☐ The proposed amendment(s) will not be entered because:

   (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

   (b) ☐ they raise the issue of new matter (see Note below);

   (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☐ The a)☐ affidavit, b)☒ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *see attached*.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☐ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowed: *none*.

   Claim(s) objected to: *none*.

   Claim(s) rejected: *1*.

   Claim(s) withdrawn from consideration: *none*.

8. ☐ The drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10. ☐ Other: _____

SUSAN UNGAR, PH.D
PRIMARY EXAMINER

1. The Amendment-after-Final filed January 23, 2004 in response to the Office Action of October 23, 2003 is acknowledged and has been entered. Previously pending claim 1 has been amended. Claim 1 is currently being examined.

2. The following rejections are maintained:

Claim Rejections - 35 USC § 102

3. Claim 1 remains rejected under 35 USC 102(a) and 102(e) for the reasons previously set for in the paper mailed October 23, 2003, Section 5, pages 3-4.

Applicant states that an exhibit is provided which is a copy of the amino acid sequence encoded by SEQ ID NO:1. Applicants have compared this sequence to polypeptides taught in US Patent 5,733, 748 and they are different. Applicant states that as evidenced by the sequence submitted herewith the CSG protein encoded by SEQ ID NO:1 is patentably different from the CSG proteins taught by US Patent No. 5,733,748.

The argument has been considered but has not been found persuasive, although Applicant has submitted a copy of the encoded protein and states that the sequences of the encoded protein and those of US Patent No. 5,733,738 are different, no objective evidence has been provided for Examiner's consideration that demonstrates these differences. Nothing has been submitted that would provide a basis for Applicant's assertion. Applicant has not met the burden to prove that the claimed method of assaying CSG protein encoded by SEQ ID NO:1 is different from that taught by the prior art or established patentable differences and in the absence of objective evidence, the claimed method appears to be the same as the prior art method.

The arguments have not been found persuasive and the rejection is maintained.

Claim Rejections - 35 USC § 112

4. Applicant argues that the potential three to four amino acid regions of overlap shown in the alignments provided by Examiner would not result in similar epitopes between HSV proteins and the CSG of the present invention. Further, the symptoms of HSV infection are different from the symptoms of colon cancer, thus, even is there were some overlap in detection of the two, the skilled clinician could still differentiate diagnostically in a patient based upon other factors. The argument has been considered but has not been found persuasive because Applicant is arguing limitations not recited in the claims as currently constituted, the claim is drawn to a method for diagnosing the presence of colon cancer based only on levels of CSG encoded by SEQ ID NO:1. Further, given the multiple epitopes in common between the HSV proteins and the CSG of the present invention, cross antibody cross reactivity would be expected.

Applicant argues that when comparing the encoded amino acid sequence of SEQ ID NO:1 with HSV 1 and 3, Applicant does not see any overlapping amino acid regions nor shared epitopes of said encoded amino acid and herpes virus 1 and 3. The arguments have been considered but have not been found persuasive. The alignments provided by Examiner clearly demonstrate the epitopes shared by the encoded polypeptides based on search of the STIC databases using the CRF of SEQ ID NO: 1 submitted by Applicant. Given this information, it would appear that the sequence comparison that Applicant refers to is not drawn to a polypeptide encoded by the SEQ ID NO:1 submitted by Applicant.

Applicant argues that (a) the references cited in the rejection are not representative of what is believed by those skilled in the art and further argues that the field is predictable given the teachings of US Patent No. 5,733,748, (b) Patent

5,733,748 teaches CSGs and proteins encoded thereby and methods of using said polypeptides for colon cancer diagnosis and this references establishes that for colon specific genes, those skilled in the art expect a correlation between polynucleotide and polypeptide, (c) the specification provides methods of detecting CSGs of the present invention. The arguments have been considered but have not been found persuasive because (a')(b') the field is not predictable for the reasons of record, the 5,733-748 reference does not establish that for colon specific genes a correlation would be expected between polynucleotide and polypeptide. Applicant is invited to point to the column and line where this particular teaching is to be found, (c') the teaching in the specification is not commensurate in scope with the claimed invention for the reasons of record. It is noted that Applicant has not addressed the issue previously raised as to whether or not the protein product is a cell surface protein or whether it is released into bodily fluids.

The arguments have not been found persuasive and the rejection is maintained.

SUSAN UNGAR PH.D
PRIMARY EXAMINER